UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION; STATE OF NEW YORK; STATE OF CALIFORNIA; STATE OF ILLINOIS; STATE OF NORTH CAROLINA; STATE OF OHIO; COMMONWEALTH OF PENNSYLVANIA; and COMMONWEALTH OF VIRGINIA,

Plaintiffs,

v.

VYERA PHARMACEUTICALS, LLC; PHOENIXUS AG; MARTIN SHKRELI, individually, as an owner and former director of Phoenixus AG and a former executive of Vyera Pharmaceuticals, LLC; and KEVIN MULLEADY, individually, as an owner and director of Phoenixus AG and a former executive of Vyera Pharmaceuticals, LLC,

Defendants.

Case No. 20-cv-00706 (DLC)

ECF Case

DEFENDANTS' REPLY MEMORANDUM ADDRESSING AN UNANTICIPATED LEGAL ARGUMENT RAISED IN PLAINTIFFS' PRETRIAL MEMORANDUM OF LAW

As permitted by the Court's Individual Practices in Civil Cases and the Order of April 1, 2021 (ECF No. 409), Defendants Vyera Pharmaceuticals, LLC, Phoenixus AG, Kevin Mulleady, and Martin Shkreli (collectively, "Defendants") respectfully submit this reply memorandum to address an unanticipated legal argument in Plaintiffs' Pretrial Memorandum of Law.

PRELIMINARY STATEMENT

Defendants have anticipated and addressed all of the legal arguments that Plaintiffs raised in their Pretrial Memorandum of Law save for one. Defendants did not anticipate that Plaintiffs would ignore entirely the governing legal standard for rule of reason claims articulated by the Supreme Court in *Ohio v. American Express Co.*, 138 S. Ct. 2274 (2018). In *American Express*, the Supreme Court held unequivocally that a government plaintiff pursuing a rule of reason claim must prove that the challenged conduct caused "a substantial anticompetitive effect that harms consumers in the relevant market." *Id.* at 2284.[1] There is no question that this is the standard that governs all claims in this case.

Plaintiffs not only fail to cite *American Express*, but they also do not acknowledge their burden under the rule of reason as articulated by the Supreme Court. Instead, they invite error by pressing a more lenient standard, citing inapposite Circuit Court decisions decided before *American Express*. Because this is a fundamental threshold issue that is dispositive of all of Plaintiffs' claims, Defendants address it here.

ARGUMENT

Plaintiffs challenge three types of commercial arrangements in this case. As to each, their only conceivable theory of anticompetitive effects resulting in harm to *consumers*, as opposed to harm to Vyera's *competitors*, is purported overpayments allegedly resulting from

[1] In *NCAA v. Alston*, 141 S. Ct. 2141, 2160 (2021), the Supreme Court more recently confirmed that this is the same standard that applies to claims brought by private plaintiffs under the rule of reason.

delayed generic competition. Because pharmaceutical companies cannot sell generic Daraprim without FDA approval, at a minimum, Plaintiffs therefore must prove that generics would have received FDA approval earlier but for the challenged conduct. Without such proof, Plaintiffs have no way of establishing what *American Express* requires: substantial anticompetitive effects that harm consumers in the relevant market. There is no special rule for government plaintiffs, and there is no general obligation under the antitrust laws for companies to make it easier or less expensive for would-be competitors to compete.

In *American Express*, like here, government plaintiffs challenged commercial conduct under the rule of reason. Specifically, government plaintiffs challenged provisions in American Express's agreements with merchants that prohibited the merchants from encouraging consumers to use other credit cards that imposed lower transaction fees. The government plaintiffs provided evidence that the challenged provisions had resulted in higher merchant fees, but they failed to sustain their claims because they provided no evidence that the provisions *caused substantial anticompetitive effects* that *harmed consumers* in the relevant market for credit card transactions. *See* 138 S. Ct. at 2284.

Plaintiffs cannot avoid this standard by ignoring it.

I. Plaintiffs Fail to Show That Class of Trade Provisions in Distribution Agreements Caused Substantial Anticompetitive Effects

Plaintiffs allege that the class of trade provisions in Vyera's agreements with its distributors were the "primary plank" in the alleged "scheme," and that the provisions were "designed" to make it more difficult for generic manufacturers to acquire Daraprim samples they needed to develop a generic product. *See* Pls.' Pretrial Mem. of Law ("Pls.' Mem.") at 25-26. But Plaintiffs disclaim any obligation to prove that the provisions *actually had that effect*, much less that it was substantial and resulted in harm to consumers.

Plaintiffs rely heavily on the Second Circuit's decision in *New York ex rel. Schneiderman v. Actavis plc*, 787 F.3d 638 (2d Cir. 2015) ("*Namenda II*"). But that case provides no support for their theory, and it does not—and could not—establish a different standard under the rule of reason than the one articulated in *American Express* three years after *Namenda II* was decided. In *Namenda II*, the Second Circuit affirmed the district court's issuance of a preliminary injunction premised on a "novel" theory challenging conduct that threatened to perpetuate exclusivity through the introduction of successive products designed to treat the same condition—a practice known as "product hopping." 787 F.3d at 643. Specifically, the defendant intended to withdraw its original formulation of a drug from the market in order to coerce consumers to switch to its new formulation as to which there was no approved generic—a so-called "hard switch" or "forced switch"—and thereby foreclose generic competitors from taking advantage of state drug substitution laws that allow generics to compete without engaging in the type of marketing and promotion that is characteristic of branded pharmaceuticals. *Id.*

The Second Circuit recognized that whether this conduct violated the Sherman Act was "an issue of first impression in the circuit courts" and that it turned on the "idiosyncratic market characteristics" resulting from state drug substitution laws, as well as "some peculiar characteristics of treatment for Alzheimer's disease." *Id.* Relying specifically on cases involving antitrust claims based on product redesign, the court held that "product redesign is anticompetitive when it coerces consumers and impedes competition." *Id.* at 652-53. Because the court concluded that state drug substitution laws provided the only effective means by which the generic competitors could distribute their products, it held that the defendant's planned conduct "crosse[d] the line from persuasion to coercion" and would result in demonstrable harm to consumers. *Id.* at 654-55.

The "hard-switch" product hopping theory addressed in *Namenda II* is miles apart from Plaintiffs' challenge to the class of trade provisions here, and that case and this one are polar opposites on the facts. Here, in order to sustain their "refusal to deal" challenge to the class of trade provision, Plaintiffs must establish that Defendants abandoned a preexisting and voluntary practice of distributing Daraprim without class of trade provisions or of selling directly to generic competitors. *See In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 134-35 (2d Cir. 2014); *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 603 (1985). *American Express* requires that they must then prove that this conduct caused substantial anticompetitive effects that harmed consumers in the relevant market. *Namenda II* simply does not address this theory, much less purport to rewrite settled law on refusals to deal and vertical class of trade restrictions. And, even setting aside these critical distinctions, the claims in *Namenda II* were based on the defendant's decision to *discontinue* a prior course of dealing, purportedly done for the sole purpose of foreclosing generic competition, that plainly would have had a coercive effect on consumers. In other words, unlike here, the plaintiff in *Namenda II* (the State of New York) was not seeking to force the defendant to do something it had not previously done so that it would be easier and/or less expensive for competitors to compete, but rather to prevent the defendant from actively coercing consumers to use its new product by withdrawing its original product from the market in order to prevent pharmacies from substituting FDA-approved generics.

Plaintiffs further argue that under *Namenda II* they are not "required to disprove that some independent event, such as FDA delays, might have contributed to generic entry delays," and that it is sufficient for them to show that generic manufacturers were barred from the most "cost-efficient" means of obtaining Daraprim samples. Pls.' Mem. at 28 & n.13 (citing *Namenda II*, 787 F.3d at 652, 656). *Namenda II* offers no support for this argument. The plaintiff's claim

in *Namenda II* was not that the challenged conduct made it more expensive for generic firms to distribute a competing product. Rather, the claim was that the challenged conduct foreclosed the *only* effective avenue for generic competition—operation of state drug substitution laws. *Namenda II*, 787 F.3d at 655-56; *id.* at 656 ("[A]dditional expenditures by generics on marketing would be impractical and *ineffective*." (emphasis added)). Plaintiffs do not even allege such complete foreclosure here, and the record is to the contrary. The fact that some generic manufacturers had to pay more than they would have liked, or allegedly had to purchase from one of the many procurement firms that offered to sell samples rather than purchase from Vyera or one of its distributors directly, does nothing to meet Plaintiffs' burden of showing the requisite substantial anticompetitive effects that harmed consumers.

Relying on two First Circuit decisions that also predate *American Express*, Plaintiffs further argue that as government plaintiffs they are not required to provide "proof that the conduct ultimately delayed competition and led to higher prices." *Id*. at 27-28 (citing *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 60 (1st Cir. 2016); *Town of Concord v. Bos. Edison Co.*, 915 F.2d 17, 21-22 (1st Cir. 1990)). Not only is that argument directly inconsistent with the standard articulated in *American Express*, but it is also not supported by the cases Plaintiffs cite. In *Town of Concord*, the First Circuit did not address the legal standard applicable to government plaintiffs. Rather, that case was brought by municipal plaintiffs against a regulated utility and involved the narrow question of whether a price squeeze violated the Sherman Act when the utility's prices were regulated at both the primary and secondary levels. 915 F.2d at 21-22. *Town of Concord* had nothing to do with a government plaintiff's burden to show substantial anticompetitive effects under the rule of reason.

Likewise, in *Nexium*, the First Circuit did not address a government plaintiff's burden to show substantial anticompetitive effects under the rule of reason. Instead, that case concerned a private plaintiff's separate burden pursuant to a different element of Sherman Act claims—to show that it suffered an antitrust injury of the type the antitrust laws were intended to prevent. 842 F.3d at 60-61. On the antitrust injury issue, the First Circuit held that there was nothing inconsistent with a jury verdict that found that the plaintiff met its burden of showing harm to competition, but failed to show that it had suffered an antitrust injury and was entitled to damages. *Id*. Here, the fact that Plaintiffs are not required to show antitrust injury does not relieve them of their burden under the Supreme Court's decision in *American Express* to prove substantial anticompetitive effects that harmed consumers in the relevant market.

In sum, as to the "primary plank" in Plaintiffs' case, none of the authorities on which they rely relieves them of their burden to prove that (1) Defendants violated some duty to deal because they abandoned a preexisting and voluntary practice of selling Daraprim in open distribution without class of trade provisions, as required to fit within the narrow exceptions identified in *Adderall* and *Aspen Skiing*, and (2) the class of trade provisions caused substantial anticompetitive effects that harmed consumers as required by *American Express*.

II. Plaintiffs Fail to Show That Exclusive API Supply Agreements with Fukuzyu and [redacted] Caused Substantial Anticompetitive Effects

Plaintiffs similarly allege that Vyera's API supply agreements with Fukuzyu and [redacted] prevented generic manufacturers from accessing "the most viable sources of pyrimethamine API." Pls.' Mem. at 29. Again, Plaintiffs cite *Namenda II* for the proposition that they need not show substantial foreclosure of all alternative sources of pyrimethamine API, but instead are required only to show that they were prevented from using the most "cost-efficient" sources. *Id*. at 32 (citing *Namenda II*, 787 F.3d at 656). As an initial matter, Plaintiffs have set up a straw

man by overstating Defendants' argument as requiring a showing of "total foreclosure." Pls.' Mem. at 30. Defendants have never made that argument. Rather, Defendants have argued consistently that Plaintiffs must prove that the supply agreements resulted in "substantial foreclosure" in the market for pyrimethamine API. That is the governing standard that this Court must apply, and it is a standard that Plaintiffs cannot meet. *See In re Keurig Green Mountain Single-Serve Coffee Antitrust Litig.*, 383 F. Supp. 3d 187, 234 (S.D.N.Y. 2019); *see also Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 328 (1961).

In any event, Plaintiffs' reliance on *Namenda II* is again misplaced. First, *Namenda II* had nothing to do with the substantial foreclosure standard. The court in *Namenda II* applied an entirely different legal standard that governs antitrust challenges to a defendant's product redesign. 787 F.3d at 652-53. Second, as discussed above, the means of distribution that the plaintiff alleged was foreclosed in *Namenda II* was not simply more "cost-efficient" than the alternatives—it was "*the only* cost-efficient means of competing available to generic manufacturers." *Id.* at 655-56 (emphasis added).[2] Plaintiffs make no such allegation here with respect to the broad universe of potential suppliers of pyrimethamine API, which is the relevant antitrust market for purposes of this analysis. At most, Plaintiffs allege that generic manufacturers were forced to spend "time and money working with a new manufacturer to develop a pyrimethamine API manufacturing process." Pls.' Mem. at 30. But they make no attempt to establish a causal link between the challenged API agreements and the decisions that the generic manufacturers made to select their own alternative API suppliers, much less to any

[2] Plaintiffs also omit from their discussion of *Namenda II* the Second Circuit's recognition that an agreement cannot trigger liability under Section 1 of the Sherman Act unless the agreement itself unreasonably restrains trade *and* "there is mutual anticompetitive intent." *Namenda II*, 787 F.3d at 660 (citing *Geneva Pharms. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 506-07 (2d Cir. 2004)). There is no evidence in the record that can meet either the required element of anticompetitive effects *or* the required element of "mutual anticompetitive intent" with respect to either Vyera's distributors or the counterparties to Vyera's API supply agreements.

substantial anticompetitive effects on consumers of Daraprim resulting from delayed generic competition—which is the showing they are required to make under *American Express*.

Plaintiffs' position is not only at odds with controlling law, but it is also completely undercut by the facts. For Cerovene, for example, the evidence shows—and Plaintiffs grudgingly acknowledge (*id.* at 8 & n.2)—that Cerovene obtained all the API it needed in order to file its ANDA, obtain FDA approval, and launch its generic product, and that it obtained this API from [redacted] pursuant to [redacted]. Defs.' Mem. Addressing Questions of Law Likely to Arise at Trial, at 29-30. Cerovene has obtained additional pyrimethamine API [redacted] since entering the market, and has also secured a backup supply of pyrimethamine API [redacted]. *Id.* Cerovene also *turned down* [redacted] offer to supply Cerovene with pyrimethamine API in 2015, more than a year before Vyera entered its own agreement with [redacted]. *Id.* Likewise, Fera selected [redacted] as its API supplier in 2016—the year *before* Vyera entered into its supply agreements with Fukuzyu and [redacted]—so whatever drove Fera's selection of [redacted], it could not have been the challenged agreements with Vyera. *Id.* at 30-31. Further, [redacted] entered into a supply agreement with [redacted] *before* Vyera entered into its supply agreement with [redacted], and [redacted] was subsequently able to obtain pyrimethamine API from Bal Pharma. *Id.* at 27-28. Mylan obtained pyrimethamine API from [redacted] in 2017 and refused offers for more after it put its generic Daraprim project on hold. *Id.* at 31-32. Finally, Teva—the generic manufacturer Plaintiffs ignore entirely—was able to obtain pyrimethamine API from [redacted] without any difficulty at all. *Id.* at 32. In light of these facts, there is simply no possible way for Plaintiffs to establish that the challenged supply agreements resulted in "substantial foreclosure" of the market for pyrimethamine API.

III. Plaintiffs Fail to Show That Agreements Restricting Distributors from Selling Daraprim Sales Data to Third-Party Data Aggregators Caused Substantial Anticompetitive Effects

Here again, Plaintiffs focus on alleged *intent* rather than on evidence of *actual effects* necessary to meet their burden under *American Express*. Specifically, they argue that in order to "stymie potential entry, Vyera paid two of its primary distributors not to sell their Daraprim sales data to third-party aggregators, like IQVIA." Pls.' Mem. at 32. They make no attempt to establish that these agreements caused any substantial anticompetitive effects that harmed consumers in the relevant market. Plaintiffs cite *United States ex rel. Krahling v. Merck & Co.*, 44 F. Supp. 3d 581 (E.D. Pa. 2014), for the proposition that the "type of deterrence" that Plaintiffs allege was *intended* by the agreements "can violate the antitrust laws." Pls.' Mem. at 33. But that decision does not support Plaintiffs' claims at all. There, the plaintiff alleged that the defendant made misrepresentations to the FDA concerning the efficacy of its vaccine and that these fraudulent misrepresentations secured the defendant's monopoly. *Krahling*, 44 F. Supp. 3d at 598-99. Here, there are no alleged misrepresentations to the FDA or to anyone else—just restrictions on the sale of data concerning Vyera's own product—and more importantly there is no evidence that those restrictions caused substantial anticompetitive effects that harmed consumers.

CONCLUSION

In order to prevail on any of their claims, Plaintiffs must meet the standard articulated by the Supreme Court in *American Express* and establish that the challenged conduct caused "a substantial anticompetitive effect that harms consumers in the relevant market." 138 S. Ct. at 2284. Plaintiffs' failure even to address that standard in their Pretrial Memorandum of Law, and their reliance instead on inapposite decisions that predate the Supreme Court's decision, simply underscores that Plaintiffs are unable to satisfy their burden under that standard at trial.

Dated: October 27, 2021

Respectfully submitted,

/s/ Kenneth R. David
Kenneth R. David
KASOWITZ BENSON TORRES LLP
1633 Broadway
New York, NY 10019
Telephone: (212) 506-1893
kdavid@kasowitz.com

Counsel to Defendant Kevin Mulleady

/s/ Christopher H. Casey
Christopher H. Casey (pro hac vice)
DUANE MORRIS LLP
30 South 17th Street
Philadelphia, PA 19103
Telephone: (215) 979-1155
chcasey@duanemorris.com

Counsel to Defendant Martin Shkreli

/s/ Steven A. Reed
Steven A. Reed (pro hac vice)
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: (215) 963-5000
Fax: (215) 963-5001
steven.reed@morganlewis.com

Stacey Anne Mahoney
MORGAN, LEWIS & BOCKIUS LLP
101 Park Avenue
New York, NY 10178
Telephone: (212) 309-6000
Fax: (212) 309-6001
stacey.mahoney@morganlewis.com

Counsel to Defendants Vyera Pharmaceuticals, LLC and Phoenixus AG

CERTIFICATE OF SERVICE

I certify that on October 27, 2021 a copy of the foregoing Defendants' Memorandum Addressing an Unanticipated Legal Argument Raised in Plaintiffs' Pretrial Memorandum of Law was served upon all counsel of record.

/s/ Noah J. Kaufman